K002611

OCT 31 2000

GE Medical Systems

P.O. Box 414, W-709
Milwaukee, WI 53201
USA

SUMMARY OF SAFETY AND EFFECTIVENESS

- This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- Identification of Submitter
  Larry A. Kroger, Ph.D., 262-544-3894, August 16, 2000

- Identification of the Product
  Signa MFO/*i* Magnetic Resonance System

  Manufactured by: GE Yokogawa Medical Systems, Ltd.
  4-7-127, Asahigaoka, Hino-Shi
  Tokyo, 191-8503 Japan

- Marketed Devices

  The Signa MFO/*i* Magnetic Resonance System is substantially equivalent to the currently marketed Signa OpenSpeed Magnetic Resonance System with the main difference being a 0.35T Open Magnet while the Signa OpenSpeed System (K992746) has a 0.7T Open Magnet. The magnets look similar.

- Device Description

  The Signa MFO/*i* Magnetic Resonance System is a high resolution, whole-body imaging system using an innovative open magnet design operating at 0.35T. The Signa MFO/i Magnetic Resonance System is designed to provide openness and patient comfort for a wide range of examinations, while providing diagnostic image quality. The Signa MFO/i Magnetic Resonance System provides performance of routine and specialized clinical examinations including the central nervous system, body, joints, extremities and vascular anatomy.

- Indications for Use

  The Signa MFO/*i* system is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The MFO/*i* system is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures and organs of the entire body, including, but not limited to, the musculocskeletal, vascular, cardiac, and neuro systems. The images produced by the MFO/*i* system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

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Due to the 'open' design of the system, the MFO/*i* may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in-room display and MR safe biopsy needles.

° Comparison with Predicate

The Signa MFO/*i* Magnetic Resonance System is comparable to the Signa OpenSpeed Magnetic Resonance System with the main difference being the magnet strength. The Signa MFO/*i* Magnetic Resonance System magnet is 0.35T permanent magnet instead of 0.7T superconducting magnet used in the Signa OpenSpeed System (K992746).

° Summary of Studies

The Signa MFO/*i* Magnetic Resonance System was evaluated to the appropriate NEMA performance standards as well as the IEC 601-1 International medical equipment safety standard and IEC 601-2-33 Particular requirements for the safety of magnetic resonance equipment for medical diagnosis. The Signa MFO/*i* Magnetic Resonance System is comparable to the Signa OpenSpeed Magnetic Resonance Systems.

° Conclusions

It is the opinion of GE that the Signa MFO/*i* Magnetic Resonance System is substantially equivalent to the Signa OpenSpeed Magnetic Resonance Systems. The Signa MFO/*i* Magnetic Resonance System does not include any new indications for use, nor does use of this device result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2000

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems, Inc.
P.O. Box 414, W-709
Milwaukee, WI 53201

Re: K002611
Signa MFO/I Magnetic Resonance System
Dated: August 21, 2000
Received: August 22, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K00 2611

Device Name: Signa MFO/*i* Magnetic Resonance System

Indications for Use:

The Signa MFO/*i* system is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The MFO/*i* system is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures and organs of the entire body, including, but not limited to, the musculocskeletal, vascular, cardiac, and neuro systems. The images produced by the MFO/I system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

Due to the 'open' design of the system, the MFO/*i* may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in-room display, and MR safe biopsy needles.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use x OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002611